IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

DAVID ZINK, et al.,	)	
Plaintiffs,	)	
	)	
v.	)	**No. 2:12-CV-4209**
	)	
GEORGE A. LOMBARDI, et al.,	)	
Defendants.	)	

MOTION TO AMEND THE SCHEDULING ORDER

On June 26, 2012, Plaintiffs brought suit in the Circuit Court of Cole County to challenge the execution protocol that Defendants had announced the previous month. Columbia University anesthesiologist Mark J.S. Heath, M.D., explained that, among other problems, the protocol risked severe and excruciating pain because Defendants planned to inject fifteen times the standard clinical amount of propofol—a drug that is often painful during routine surgeries, and which has never been used to carry out an execution. *See* ECF Doc. 1, Ex. A, Ex. 1 ¶¶ 25-36. Over the next thirteen months, Defendants removed the case to this Court, filed two unsuccessful motions to dismiss, and delayed discovery through objections that the Court rejected after extensive briefing and an aborted interlocutory appeal. ECF Docs. 68, 78, 101, 104. Throughout, Defendants refused to specify how they might change the protocol, even as late as Defendant Dave Dormire's deposition of July 16, 2013. *See* Ex. 1, at 27-28. Defendants finally disclosed a new protocol on August 2, 2013, two weeks **after** the close of discovery. Five days later, they moved for summary judgment, arguing that their post-discovery replacement protocol had definitively and dispositively cured the flaws of its 2012 predecessor. ECF Doc. 116, at 3; Doc. 117, at 10-14.

Defendants' contention is startlingly premature. Plaintiffs have had no discovery concerning the new protocol, do not know how it was conceived or any

scientific basis underlying it, cannot determine the meaning of critical provisions of the new protocol, and have not had a reasonable opportunity to amend their pleading, to obtain a supplemental expert report, or to develop their case for summary judgment and trial. What is more, the new protocol creates new problems beyond those it purports to solve, and Dr. Heath remains "highly confident that if the current lethal injection protocol is carried out, it will inflict gratuitous severe pain on many of the prisoners who are subjected to it." Ex. 2 (Declaration) ¶ 5. Faced with a brand new protocol, Plaintiffs must be afforded the opportunity to demonstrate its defects. Plaintiffs ask the Court to stay the motion for summary judgment, to afford Plaintiffs 30 days to amend their complaint and 90 days for discovery, and to extend the dates for dispositive motions and trial accordingly. These extensions are modest in comparison to the nine months of discovery that were permitted by the original scheduling order. *See* ECF Doc. 1 (removal on August 1, 2012); ECF Doc. 28 (discovery deadline of April 25, 2013).

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FACTUAL BACKGROUND

1. On May 15, 2012, the Department of Corrections announced the world's first-ever execution protocol using propofol as a lethal agent. *See* ECF Doc. 1, Ex. A, Ex. 1 (Heath Affidavit Ex. 2). The protocol stated that "medical personnel" would oversee "nonmedical personnel" in injecting two grams of propofol into the prisoner. *Id.* ¶¶ A.3-4, B.2. The two grams of propofol were divided into four syringes containing 50 cc of the drug, with the first syringe also containing 10 cc of the analgesic lidocaine. *Id.* ¶¶ B.2., E.1 - E.3.

2. On June 26, 2012, Plaintiffs filed a petition in the Circuit Court of Cole County, attacking the protocol under the Eighth and Fourteenth Amendments to the United States Constitutions as well as their Missouri analogues; the Ex Post Facto provisions of both Constitutions; the Supremacy Clause by virtue of Defendants' violation of the Food, Drug and Cosmetic Act; and the separation of powers guaranty of Mo. Const. art. II, § 1. Plaintiffs provided sworn expert evidence from Dr. Heath, who explained that propofol creates the risk of excruciating pain in medical settings, that Defendants intended to inject the condemned with approximately 15 times the clinical dosage of propofol, that the greater dosage of propofol heightened the risk of pain, and that neither lidocaine nor any other clinically-used technique could reliably prevent propofol-evoked pain—even from a clinical dosage administered solely by licensed, experienced health-care professionals. *See* ECF Doc. 1, Ex. A, Ex. 1 (Heath Affidavit) ¶¶ 25-36. For over one year, then, Defendants have been on notice of Dr. Heath's teaching that an increase in the amount of propofol would enhance the already significant pain experienced in the clinical setting by "many patients." *Id.* ¶ 32.

3. On August 1, 2012, Defendants removed the case to this Court.

4. On November 16, 2012, the Court partly granted and partly denied Defendants' motion to dismiss. ECF Doc. 31. Although the Court dismissed the Supremacy Clause and separation-of-powers claims on the facts then before it, it declined to dismiss the remaining claims in light of the risks Plaintiffs had documented. Defendants later moved for judgment on the pleadings, but the Court adhered to its previous rulings in an order dated March 25, 2013. ECF Doc. 61.

5. The parties undertook substantial discovery, including depositions of Dr. Heath, executioner-anesthesiologist M3, executioner-nurse M2, and D.O.C. Director of Adult Institutions Dave Dormire, as well as interrogatories and requests for production of documents. These measures required considerable time and litigation, as Defendants' many objections to legitimate discovery requests were presented to the Court and rejected. *E.g.*, ECF Docs. 68, 78, 101, 104.

6. Throughout discovery, Plaintiffs litigated their claims on the evidence Defendants presented to them: that Defendants intended to use their protocol of May 15, 2012. Despite the duty to supplement discovery under Rule 26(e), Defendants did not disclose any actual or proposed amendments to the protocol. To the contrary, they insisted as recently as last month that they were ready to carry out the **2012** protocol against Plaintiffs Allen Nicklasson and Joseph Franklin. *See State v. Nicklasson*, Mo. Supreme Court Case No. SC79163; *State v. Franklin*, Mo. Supreme Court Case No. SC79735 (Renewed Motions to Set Execution Date, dated July 1, 2013; Reply Suggestions in Support of Renewed Motions, dated July 15, 2013).

7. On July 16, 2013, Plaintiffs took the deposition of Dave Dormire. Mr. Dormire testified that he believed "we do need to make some amendments" to the protocol. *See* Ex. 1 (Dormire Deposition), at 27-28. Plaintiffs' counsel asked Mr.

Dormire what amendments might be made and when. *Id.* At that time, just two weeks before Defendants issued a new protocol and less than three weeks before the summary judgment deadline, Mr. Dormire answered that he did not know when any changes might be made. Defense counsel specifically instructed Mr. Dormire not to answer when Plaintiffs' counsel asked him to specify the changes themselves. *Id.* at 28. According to defense counsel, any changes to the protocol amounted to "work product" until Defendants had formally reflected them in an amended protocol. *Id.* at 28. This invocation of "work product" itself contradicted Defendants' earlier practice. In his interrogatory responses, Mr. Dormire did not object to a question concerning methods of execution that Defendants considered adopting other than the propofol-protocol of 2012. *See* Ex. 3 (Defendant Dormire's Answers to Interrogatories), at 10 ¶ 13 ("We examined methods utilized by other states.").

8. On August 1, 2013, Defendants issued a new execution protocol and accompanying affidavit, which are attached as Exhibits 4 and 5. Defendants emailed the protocol to Plaintiffs' counsel and the Court the next day.

9. On August 7, 2013, Defendants moved for summary judgment, pointing to three changes in the new protocol. ECF Docs. 116, 117. First, the initial syringe now contains 20 cc of propofol, or what Defendants describe as a "clinical" dosage (along with lidocaine). ECF Doc. 117, at 4 & 9-10. Second, unspecified "medical personnel" will check the prisoner's consciousness after the initial dosage. *See* Ex. 4 ¶ E.4. If "medical personnel" have "confirmed" that the prisoner is unconscious, the "non-medical personnel" administer the remaining propofol through four additional syringes until a total of two grams have been injected. *Id.* ¶ E.6. Third, according to Mr. Dormire's affidavit (but not the protocol), the prisoner will "receive" a "clinical

dose" of midazolam or a "similar sedative" at some unspecified point before the administration of the propofol and lidocaine. *See* Ex. 5 ¶ 6. Defendants argue that the prisoner will be sedated before he is injected with a lethal amount of propofol, and that the new protocol therefore eliminates one of the problems identified by Dr. Heath, which is that a massive dosage of propofol enhances the risk of pain on injection. ECF Doc. 116, at 3; Doc. 117, at 10-14.

10. Exhibit 1 to this motion is a declaration from Dr. Heath, who describes numerous problems with the new protocol:

●Central line access – Defendants appear to retain the grisly practice, announced earlier in the litigation, of carving out a central line access before each and every execution. Central line access is "inherently more invasive" than peripheral IV access, and, under the protocol's sub-clinical circumstances, it presents foreseeable complications that are likely to result in "extreme pain and suffering." *Id.* ¶¶ 18-20. These include collapsing the lung and suffocating the prisoner; perforating the heart, a central blood vessel, the carotid artery, or the bowel or bladder; and cardiac arrhythmia resulting in hemodynamic collapse and death. *Id.* ¶ 18. These risks are elevated when the patient is agitated, uncooperative, or struggling. *Id.* ¶ 19. They are foreseeable and inevitable "when conducted on a large series of patients," and yet Defendants do not have the suitable diagnostic and therapeutic equipment or drugs to detect and correct these severely painful adverse events. *Id.* ¶ 20.

●Midazolam – The new protocol and accompanying affidavit involve the sedative midazolam in ambiguous and troubling ways. The protocol does not even mention the drug. That gloss is only found in the affidavit of Mr. Dormire, who has no medical training, and who does not specify what he considers to be a "clinical

dose" of midazolam. In Dr. Heath's practice, such a dose may vary from 0.25 mg to 20 mg, i.e. by a factor of eighty, depending on the reason for administering it. *Id.* ¶ 24. Mr. Dormire says only that the sedative will be given "prior to the administration" of propofol and lidocaine. He does not specify whether the prisoner will be sedated hours beforehand (as with the oral Valium given by the nurse under the three-drug protocol in *Ringo v. Lombardi*, No. 09-4095-CV-C-NKL, ECF Doc. 263, at 7), or whether the midazolam "or similar sedative" will be administered immediately before the other drugs. Nor do the new protocol and affidavit specify whether the midazolam, like the propofol and lidocaine, will be administered by prison guards instead of qualified anesthesia personnel, whether it will be given intravenously or otherwise, whether the amount of midazolam might undermine the prisoner's ability to comprehend the ensuing execution, or what "similar" sedative might replace it . Ex. 2 ¶¶ 24-26. And even under the best of circumstances, midazolam carries side-effects that would be degrading and dehumanizing on execution night, including "disorientation, agitation, dis-inhibition, and other behaviors and experiences that are disturbing to the prisoner, staff, and witnesses." *Id.* ¶ 26.

● The consciousness check – The consciousness check inserted into the protocol is defective. The new protocol does not specify which "medical personnel" will check the prisoner's consciousness. *Id.* ¶ 15, 21-23. It does not specify that anesthesiologist M3 will perform this task, as opposed to M2—a licensed practical nurse who lacks the professional experience and credentials to do so—or even whether the "medical personnel" will be in the same room as the prisoner and able to view the EKG monitoring equipment. *Id.* Dividing the propofol into a "clinical" dose and a lethal dose "is only meaningful if a reliable process is in place to ensure that the

initial dose of propofol produced the intended effect of un-arousable unconsciousness" Dr. Heath explains. *Id.* ¶ 23.

●Pain from propofol – More generally, the risk of pain from the protocol would remain gratuitous and unacceptable even if Defendants could guarantee that the risk equates to that of routine surgical anesthesia. Even under ideal clinical circumstances, there is no reliable means to reduce the known likelihood of extreme pain from a propofol injection. Dr. Mark Dershwitz—Defendants' expert in earlier litigation—testified that a subset of patients will inevitably "scream at the top of their lungs." ECF Doc. 1, Ex. A (Petition ¶ 147 & Ex. 4). Dr. Heath has the "highest degree of medical certainty that if the current protocol is used by the MDOC, it will directly cause some prisoners to experience their final moments of consciousness in severe pain." Ex. 2 ¶ 8. Such executions will be ghastly: "The prisoner will be moaning or shouting or screaming and/or writhing, it will be clearly evident to the witnesses and staff, and there will be nothing to be done about it except to wait until the drug circulates to the brain and produces unconsciousness." *Id.* Dr. Heath explains that a subset of the patients suffer severe pain with propofol, but it is not possible to predict which patients these are. *Id.* Nevertheless, "[I]t is absolutely foreseeable and certain that some of the executions will be painful." *Id.*

The risk of propofol-evoked pain is "acceptable" in routine medical practice only because of the corresponding medical benefit of surgery, the easy recuperation that propofol allows after surgery, and the patient's informed consent to propofol and its risks—none of which exists during an execution, which, unlike surgeries, need not entail pain-provoking propofol at all. *Id.* ¶¶ 12, 13. Moreover, Defendants fail to use accepted clinical methods to reduce the risk of pain from propofol, including the

use of a "powerful narcotic agent" such as fentanyl to produce "a state of sedation and analgesia," or lidocaine in combination with a tourniquet. *Id.* ¶¶ 7, 12.

11. Plaintiffs have consulted defense counsel, who states that Defendants are willing to reopen discovery but oppose any deadline extensions or other measures that would involve continuing the trial date of October 7, 2013, which the Court adopted before Defendants changed their protocol after the close of discovery.

Argument: Defendants' newly-issued protocol provides ample "good cause" to amend the scheduling order.

I. Plaintiffs had no notice of the new protocol until Defendants disclosed it on August 2, and the new protocol introduces new material facts that alter and broaden the prisoners' claims.

Defendants announced a new protocol just over two weeks ago, and Plaintiffs legitimately seek to investigate and allege new claims, document them on summary judgment, and prove them at trial. Rule 16(b)(4) allows the Court to modify its scheduling order for "good cause," which depends primarily on the moving party's diligence. *E.g.*, *Sherman v. Winco Fireworks*, 532 F.3d 709, 716–17 (8th Cir. 2008); *Scheidecker v. Arvig Enterprises*, 193 F.R.D. 630, 631-33 (D. Minn. 2000). Plaintiffs seek to modify the scheduling order at the earliest opportunity, as they said they would during the teleconference with opposing counsel and Judge Whitworth on August 12.

The moving party generally shows "good cause" when it relies on newly-disclosed facts or newly-committed wrongs. In *Soroof Trading Dev. Co. v. GE Microgen*, 283 F.R.D. 142 (S.D.N.Y. 2012), for example, the court allowed the plaintiff to amend its complaint and add a new defendant under a theory of piercing the corporate veil, even though the deadline had passed for amending the pleadings. The court observed that it was only through discovery that the plaintiff learned of the

corporation's undercapitalization, lack of employees, and questionable transfers of funds, and the plaintiff moved to amend 30 days after learning of these facts. *Id.* at 149. The court allowed a similar amendment to a scheduling order in *Lincoln v. Potter*, 418 F. Supp. 2d 443 (S.D.N.Y. 2006). There, the plaintiff claimed that the Postal Service retaliated against her for alleging age discrimination. Because the retaliatory acts themselves occurred after the deadline for amending the pleadings, the plaintiff showed good cause. *Id.* at 454. To like effect is the district court's ruling in *Scheidecker*, where the defendants had been "somewhat coy" about the precise corporate identity of the plaintiff's employer. 193 F.R.D. at 632. The court found good cause to join a new defendant out of time. *Id.* at 632-33.

This case is materially similar to *Soroof*, *Lincoln*, and *Scheidecker*. Discovery ended on July 18, but Defendants did not disclose a new protocol until August 2. Moreover, Defendants were worse than "somewhat coy" about whether and how they might amend the protocol. At no point did Defendants supplement their interrogatory responses or other discovery under Rule 26(e) to disclose possible changes to a protocol that the parties had litigated for fourteen months, until defendants invented yet another new protocol five days before seeking summary judgment. Defense counsel even invoked the work product doctrine and instructed Mr. Dormire not to discuss alternative protocols during his deposition. Ex. 1, at 28. Plaintiffs were ignorant of the new protocol through no fault of their own, and thus, unable to consult their expert, plead new claims, or pursue additional discovery.

II. Plaintiffs reasonably require additional discovery and claim development.

Plaintiffs require further discovery in order to be fully and fairly heard. For one thing, the new protocol is vague in critical respects. *See* Ex. 2 ¶¶ 15, 21-26. Plaintiffs need additional discovery in order to clarify how Defendants plan to carry out the latest protocol: the nature and frequency of central line access, which is an independently pain-inducing procedure; the amount, timing, and purpose of midazolam; the identities and location of "medical personnel" who perform the consciousness check; or even whether Defendants have ever rehearsed their newly-issued protocol. *See Ringo*, ECF Doc. 263, at 9-10 (noting quarterly sessions). The new protocol does not define what its supposed improvements are or how Defendants will implement them in all relevant respects. Plaintiffs seek answers from the implementers themselves; among other measures, Plaintiffs must reopen the depositions of Mr. Dormire, anesthesiologist M3, and nurse M2.

Plaintiffs must also develop further expert evidence to assess the new protocol, to present an updated expert report under Rule 26(a)(2)(B), and otherwise to respond to the motion for summary judgment and prepare for trial. Dr. Heath's preliminary assessment of the new protocol counsels against proceeding hastily. As explained above, it apparently remains Defendants' intention to insert a central line for every execution. That plan presents well-recognized and agonizing complications even under the best of hands, including lung collapse and suffocation, puncture of a major blood vessel or the heart, or perforating the bowel or bladder—risks that are elevated if the prisoner is agitated or uncooperative, and which are exacerbated by Defendants' lack of proper equipment to detect and treat them. Ex. 2 ¶¶ 18-20.

Dr. Heath is also troubled by the document's ambiguities, including its broad definition of "medical personnel," the tasks it assigns to unspecified "medical personnel" rather than an anesthesia specialist or even M3 himself, critical details of the consciousness check following the initial dosage of propofol and lidocaine, and the protocol's failure to specify the amount, timing, or clinical purpose of midazolam (to say nothing of its omission from the protocol per se). *Id.* ¶¶15, 21-26. Finally, Dr. Heath explains that the risk of propofol-evoked pain would be both substantial and medically unacceptable even if Defendants could reliably lower the risk of pain to that of routine surgical anesthesia. *Id.* ¶¶ 6-13. Plaintiffs seek additional time to document the new protocol's failures, and to identify additional problems as discovery reveals how the protocol will be carried out.

III. Plaintiffs will promptly file a supplemental complaint to show that the new protocol does not solve the problem of propofol-evoked pain, and also to demonstrate new illegalities unique to the new protocol.

Plaintiffs also intend to supplement their pleading within the coming weeks. Rule 15(d) allows a court to permit a supplemental complaint "setting out any transaction, occurrence, or event that happened after the date of the pleading to be supplemented." Plaintiffs seek to offer a pleading that accurately describes the procedure they challenge, as well as the legal implications of newly-known facts. For example, even Defendants acknowledge that the initial dose of propofol creates a risk of pain comparable to routine surgery. *See* ECF Doc. 117, at 14; ECF Doc. 84 Ex. 4, at 2 (per M3) ("A subset of the population who receives propofol will demonstrate a visible pain response at the injection site."). That pain is described as excruciating by the Defendant's former expert, Dr. Mark Dershwitz, who says that "Many patients ... scream at the top of their lungs from propofol." ECF Doc. 1, Ex. A (Petition ¶ 147 &

Ex. 4). Dr. Heath states with the "highest degree of medical certainty" that the current protocol "will directly cause some prisoners to experience their final moments of consciousness in severe pain." Ex. 2 ¶ 8.

Defendants insist that this risk is necessarily "tolerable" under the Eighth Amendment, because the same risk is "widely tolerated" in the context of routine surgery. ECF Doc. 117, at 11-14, citing *Baze v. Rees*, 553 U.S. 35, 53 (2008) ("[I]t is difficult to regard a practice as objectively intolerable when in fact it is widely tolerated."). Of course, the Defendants cite *Baze* wildly out of context. There, the Court was discussing specific **methods of execution** as "widely tolerated," and it observed that most states used a method similar to the one then at bar. *Id.* But the fact that something is "widely tolerated" in some other context does not make it an acceptable means of execution. For example, concussions and broken bones are "widely tolerated" in sports such as rodeo and skiing, but that would not justify the use of stoning or breaking on the wheel as methods of execution. Missouri's proposed method is not "widely tolerated" under *Baze*; it has never been attempted or even announced anywhere else in the world. Missouri is "the only state that deliberately uses a drug that produces pain prior to producing an anesthetic effect," explains Dr. Heath. Ex. 2 ¶ 10. Plaintiffs retain a viable Eighth Amendment claim even under Defendants' partisan rendering of the new facts. But Plaintiffs deserve the opportunity to plead, investigate, and develop that claim.

The changed protocol also gives rise to new legal claims, including:

● Anesthesia without the prisoner's consent – Defendants insist that they will administer propofol and lidocaine to reduce the risk of pain. ECF Doc. 117, at 10-14. That portion of the protocol is therefore a medical procedure serving a medical

purpose. But Mo. Rev. Stat. § 217.420.1 forbids the Department of Corrections from administering any general anesthetic without the prisoner's consent:

> Except in case of an emergency, the department shall not authorize or permit any major surgery to be performed upon or general anesthetic to be administered to any offender committed to the department unless specific written consent thereto shall first have been obtained from the offender or his parent or legal guardian if he is a minor, or, in the absence of such consent, from the court which vested legal custody of such offender in the department or the circuit court of the county where the offender is located.

There is no question that section 217.420 governs this case, despite the legislature's general allowance for executions to proceed by "lethal injection" or "lethal gas" in Mo. Rev. Stat. § 546.720.1. Section 217.420 specifically prohibits the administration of "general anesthesia" without the prisoner's "specific written consent"—or that of his legal guardian or the sentencing court if the prisoner is not competent to make his own healthcare decisions. Section 546.720 only generally permits "lethal injection," which itself need not involve a general anesthetic. Thus, the two statutes do not conflict, and even if they did, the statute that more particularly addresses anesthesia would prevail. *State ex rel. Fort Zumwalt School Dist. v. Dickherber*, 576 S.W.2d 532, 536-37 (Mo. 1979) ("A specific statute prevails over a general one.").

● A non-defined protocol – Defendants show a penchant for amending the protocol willy-nilly. The most recent protocol says nothing of midazolam or any other drug beyond propofol and lidocaine. It also permits changes in the quantities of lethal chemicals on the approval of the Director of the Department of Corrections, George Lombardi. Ex. 4 ¶ B.1. A separate affidavit of Director of Adult Institutions (David Dormire) states that the prisoner will receive a "clinical dose" of midazolam or a "similar" sedative at some undefined point before the prisoner is injected with propofol and lidocaine. Ex. 5 ¶ 6. But Mr. Dormire is not a physician, let alone an

anesthesiologist. There is no indication that this change has been approved by Director Lombardi, or indeed, that the protocol meaningfully constrains the non-Lombardi defendants from amending it at any time. Defendants even acknowledge that they will customize the non-public portions of the protocol for each prisoner and will not finalize it until after the prisoner's execution is scheduled. Ex. 6 (confidential and sealed portion of Dormire deposition), at 37-40. Because Defendants claim the ability to alter the protocol at will, the prisoner must await his death without knowing how it will come about. The result is "an immense mental anxiety amounting to a great increase of the offender's punishment," *In re Medley*, 134 U.S. 160, 172 (1890), and with it, a claim under the Eighth Amendment as well as the Ex Post Facto Clause. *Cf. Williams v. Hobbs*, 658 F.3d 842, 849-51 (8th Cir. 2011) (rejecting *Medley* claim where State pledged to inform prisoner's counsel of the method of execution, rather than retaining indefinite discretion to amend it).

The absence of a known and established protocol also offends procedural due process, which requires "meaningful and adequate notice of how [the prisoner's] rights have been affected by the changes in the execution protocol." *Hoffman v. Jindal*, No. 12–796–JJB, 2013 WL 489809, at *2 (M.D. La. Feb. 7, 2013). An ever-changeable protocol is a moving target. It frustrates the prisoners' ability to assert and meaningfully develop their claims—and under circumstances resembling those of a recent Arizona case:

> By continually making representations at the last minute regarding self-imposed, but transient, limitations on the broad discretion accorded by the protocol, the Director has both precluded the affected inmates from litigating the risk of serious harm created by the protocol itself and cabined those inmates' ability to litigate fully, after the usual discovery and opportunity to obtain expert testimony and other evidence, the actual circumstances of their own executions, and to do so in advance of the day

they will be put to death.

Lopez v. Brewer, 680 F.3d 1084, 1089-90, 1092 (9th Cir. 2012) (Berzon, J., concurring with and dissenting from denial of rehearing).

●Medical malpractice – M3 and his confederates plan to administer three drugs (midazolam, propofol, and lidocaine) for the medical purpose of preventing pain. The ameliorative measures Defendants cite are therefore a medical procedure. Yet, the medical procedure deviates from sound and accepted medical practice. It unnecessarily uses an anesthetic that is known to cause severe pain, chooses that drug without the benefit of a doctor's prescription and accompanying clinical judgment that the chosen anesthetic is best suited to serve the medical purpose of preventing pain, provides for every prisoner to suffer the carving out of a central line access, and fails to ensure that qualified medical personnel assess the anesthetized prisoner's consciousness—a "sophisticated process that is a mixture of skill, art, experience, and judgment" and requires "years of training and experience." Ex. 2 ¶ 22.

The protocol embodies sub-standard medical care. It reflects an "act or omission by the defendant that [is] not in keeping with the degree of skill and learning ordinarily used by members of the defendant's profession," and it threatens to "cause the plaintiffs' injury" because of the negligent procedure it describes. *Devitre v. Orthopedic Center of St. Louis*, 349 S.W.3d 327, 335 (Mo. 2011) (elements of malpractice claim); *see also Strong v. American Cyanamid Co.*, 261 S.W.3d 493, 516-17 (Mo. Ct. App. 2007) (holding that tort plaintiffs may rely on federal regulatory requirements, including the FDCA, to establish the "standard of care" in product liability actions), *overruled in part on other grounds by Badahman v. Catering St. Louis*, 395 S.W.3d 29, 40 (Mo. 2013). No law within Plaintiffs' knowledge forbids prospective

claims of malpractice, nor injunctive relief to prevent irreparable injury.

●Due process by deliberate indifference – M3's malpractice is of constitutional import: Plaintiffs are confined by the State and cannot choose an alternative provider to administer anesthesia in accord with accepted medical practice. "[A] physician who acts on behalf of the State to provide needed medical attention to a person involuntarily in state custody (in prison or elsewhere) and prevented from otherwise obtaining it, and who causes physical harm to such a person by deliberate indifference, violates the Fourteenth Amendment's protection against the deprivation of liberty without due process." *West v. Atkins*, 487 U.S. 42, 58 (1988) (Scalia, J., concurring).

●The Supremacy Clause, preemption, and the CSA and FDCA – Midazolam is a schedule IV controlled substance, while propofol and lidocaine are prescription-only drugs. *See* 21 C.F.R. § 1308.14; Ex. 7 (propofol packaging); ECF Doc. 1 Ex. A (Petition ¶ 159). Prison guards administer the latter two drugs, and perhaps also midazolam. Ex. 4 ¶ A.4; Ex. 5 ¶ 6. Defendants contemplate no prescription for any of these drugs, in violation of the FDCA and CSA. *See* 21 U.S.C. §§ 353(b)(1), 829(b).

These claims materially differ from those brought in Plaintiffs' original petition and dismissed by the Court's order of November 16, 2012 (ECF Doc. 31). First, the new protocol eliminates the standing issue on which the Court dismissed the lidocaine-based FDCA claim. *See* ECF Doc. 31, at 8-9. The Court observed that Plaintiffs did not plead that lidocaine itself causes pain, and did not otherwise assert an injury traceable to lidocaine. *Id.* Now, however, Defendants intend to use propofol as an anesthetic first, and then as a lethal agent later. Defendants themselves admit that propofol causes pain even in the "clinical" dose of the initial syringe. ECF Doc.

117, at 10-14. Dr. Heath agrees. *See* Ex. 2 ¶¶ 6-13. Plaintiffs therefore allege a sufficient injury as to propofol, even if not as to lidocaine. Second, Plaintiffs must ascertain whether the midazolam or "similar" drug will be administered by M3, M2, or non-medical personnel, which affects the legality of the protocol's vague use of midazolam. *See* 21 U.S.C. § 822(a). Dr. Heath points to numerous adverse effects of midazolam. Ex. 2 ¶ 26. These depend on the timing and amount of the dosage, *id.*, which further discovery will reveal.

●State-induced incompetence to be executed – The Eighth Amendment forbids the execution "of those who are unaware of the punishment they are about to suffer and why they are to suffer it." *Panetti v. Quarterman*, 551 U.S. 930, 957 (2007); *Ford v. Wainwright*, 477 U.S. 399, 422 (1986) (opinion of Powell, J.). Defendants do not specify the "clinical dose" of midazolam they plan to administer before injecting Plaintiffs with propofol and lidocaine. Ex. 5 ¶ 6. Dr. Heath notes that a "clinical dose" may be as small as 0.25 mg or as large as 20 mg, so that it can vary by a factor of eighty. Ex. 2 ¶ 24. A small dose will produce a relaxed state of mind without significant pain-blocking effect, but a large dose may provide a deep comatose effect or even death. *Id.* The protocol and affidavit do not disclose when midazolam might be given—whether moments, hours, or days before the lethal propofol. *See* Ex. 6, at 39 (Dormire denying that the D.O.C. will change the time that the prisoner is given a sedative). If Defendants plan to induce a deep comatose effect before the execution, the prisoner will be rendered incompetent: unable to understand the meaning and purpose of his own death, or to assist counsel in avoiding it.

Even if the prisoner is competent, he may be drugged so long that his execution is a "lingering death" in violation of the Eighth Amendment. *Baze*, 553 U.S.

at 49; *In re Kemmler*, 136 U.S. 436, 447 (1890). Depending on the dose, midazolam may also "produce confusion, disorientation, agitation, dis-inhibition, and other behaviors and experiences that are disturbing to the prisoner, staff, and witnesses." Ex. 2 ¶ 26. That effect would degrade the prisoners at time when their dignity is of paramount importance. *See*, *e.g.*, *Washington v. Glucksberg*, 521 U.S. 702, 743 (1997) (Stevens, J., concurring in the judgment) (explaining that the "basic concept of freedom" embraces a right to die with dignity). Here as elsewhere, Plaintiffs require further investigation and discovery.

CONCLUSION

WHEREFORE, for all of the foregoing reasons, Plaintiffs respectfully request that the Court (a) stay Defendants' motion for summary judgment as premature in light of Defendants' new execution protocol, (b) reopen discovery for a period of 90 days, (c) permit Plaintiffs to file an amended and supplemental complaint within 30 days, and (d) amend the scheduling order to provide parallel extensions of the dispositive motions deadline and the trial date, so that dispositive motions will be due 20 days after the close of discovery, and trial will be scheduled for 60 days after the dispositive motions deadline (*see* ECF Doc 102).

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was forwarded for transmission via Electronic Case Filing (ECF) this 19th day of August, 2013, to Michael J. Spillane and Stephen D. Hawke, Office of the Attorney General, P.O. Box 899, Jefferson City, Missouri 65101.

/s/ Joseph W. Luby

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